## REMARKS

Applicants acknowledge the current status of the claims, as reported in Office Action dated 02 August 2005. Claims 1-95 are pending; claims 5-8, 11, and 32-88 are withdrawn from consideration; and claims 1-4, 9, 10, 12-31 and 89-95 are under consideration.

Applicants thank the Examiner for the courtesy of Examiner's interviews, conducted on 18 October 2004 and 02 December 2004, to discuss the bases of the outstanding rejections to Applicants' application. These interviews form the bases for the present remarks.

Applicants have amended claim 4 such that the antigen provided in the method comprises the amino acid sequence TKGGQDITDFQILENQ (SEQ ID NO: 3). Applicants have canceled claims 9 and 10. These amendments are made solely to advance examination of the present application to allowance. This amendment is supported throughout the specification as filed, and no new matter is added. Applicants reserve the right to prosecute the original subject matter in a later-filed continuation application, which properly claims the benefit of this application.

Reconsideration and allowance of the pending claims in light of the following remarks are respectfully requested.

***Rejections under 35 USC §103(a)***

In the Office Action at pages 3-10, the Examiner has rejected claims 1-4, 9, 12-31 and 89-95 under 35 USC §103(a) as being unpatentable over Luger et al. in view of references disclosing specific methods for generating antibodies as follows:

At page 3, paragraph 3, claims 1-4, 9, 12-14, 16, 28, and 29, 31 and 89 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of Green, J. Immunological Methods 1999, Vol. 231, pp. 11-23. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Green with those of Luger et al. to produce humanized or chimeric antibodies to IL-1.

At page 4, paragraph 4, claims 1-4, 9, 12-14, 17, 28, 31, and 89 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of Nguyen et al., Microbiol Immunol.1997, Vol. 41(12), 231, pp. 901-907. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Nguyen et al., with those of Luger et al. to produce dual-specificity human antibodies to IL-1α and IL-1β using SCID mice reconstituted with human peripheral blood lymphocytes.

At page 5, paragraph 5, claims 1-4, 9, 12-14, 18, 28 and 31 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of Reisner et al., Tibtech, 1998, Vol. 16, 231, pp. 242-246. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Reisner et al., with those of Luger et al. to produce dual-specificity human antibodies to IL-1α and IL-1β using a mouse treated with lethal total body irradiation, followed by radioprotection with bone marrow cells of a SCID mouse, followed by engrafment with human lymphocytes.

At page 6, paragraph 6, claims 1-4, 9, 12-14, 19, 20, 24 and 31 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of Barbas et al., Proc. Nat. Acad. Sci. 1991, Vol. 88, pp. 7978-7982. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Barbas et al., with those of Luger et al. to produce dual-specificity antibodies to IL-1α and IL-1β using phage display.

At page 6, paragraph 7 claims 1-4, 9, 12-14, 19, 21 and 31 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of WO 99/36569, Wittrup et al., 1999. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Wittrup et al., with those of Luger et al. to produce dual-specificity antibodies to IL-1α and IL-1β using yeast display.

At page 7, paragraph 8, claims 1-4, 9, 12-14, 19, 21, 22 and 31 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of WO 98/49286, Iverson et al., 1998. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Iverson et al., with those of Luger et al. to produce dual-specificity antibodies to IL-1α and IL-1β using yeast display and display on bacterial cells.

At page 8, paragraph 9, claims 1-4, 9, 12-14, 19, 23 and 31 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of WO 98/31700. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of WO 98/31700 with those of Luger et al. to produce dual-specificity antibodies to IL-1α and IL-1β from recombinant libraries expressed as RNA-protein fusions.

At page 8, paragraph 10, claims 1-4, 9, 12-14, 25 and 31 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of US Patent 5,580,717, Dower et al., 1996. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Dower et al. with those of Luger et al. to produce dual-specificity antibodies to IL-1α and IL-1βfrom large recombinant libraries.

At page 11, paragraph 11, claims1-4, 9, 12-14, 26 and 31 is rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of WO 97/29131, Salfeld et al., 1997. The Examiner asserts

that it would be obvious to one skilled in the art to combine the teachings of Salfeld et al. with those of Luger et al. to produce dual-specificity antibodies to IL-1α and IL-1β by in vitro affinity maturation.

At page 9, paragraph 12, claims 1-4, 9, 12-14, 27, 31and 95 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of Babcock et al., Proc. Nat. Acad. Sci. 1996, Vol. 93, pp. 7843-7848. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Babcock et al., with those of Luger et al. to produce dual-specificity antibodies to IL-1α and IL-1β by selecting single cells secreting antibodies that bind the antigen from immunized animals.

At page 10, paragraph 13, claims 1-4, 9, 12-14, 29, 30, 31, and 90-94 are rejected under 35 USC §103(a) as being unpatentable over Luger et al. in view of Knappik et al., JMB Feb. 2000, Vol. 296, pp. 57-86. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Knappik et al., with those of Luger et al. to produce dual-specificity antibodies to IL-1α and IL-1β by CDR grafting method.

In each of the rejections of claims 1-4, 9, 12-31 and 89-95 under 35 USC §103(a), as outlined above, Luger et al. serves as a common reference. The Examiner has compiled a multitude of references disclosing a variety of methods for generating antibodies and used these in view of Luger et al. to reject the claims. Applicants respectfully disagree. Applicants' basis for traversal provided below is the same for each rejection.

**THE LEGAL STANDARD FOR *PRIMA FACIE* CASE OF OBVIOUSNESS:**

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all claim limitations. Second, there must be a reasonable expectation of success. Finally, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. (see generally MPEP § 2143).

Hindsight reconstruction of a claimed invention, absent a teaching or suggestion in the art is impermissible. (MPEP § 2142).

It is well established in case law that to establish obviousness by combining or modifying the teachings of the prior art to produce the claimed invention there must be some **evidence**, implicit or explicit, of suggestion, teaching or motivation in the prior art to make the claimed invention. Merely showing that all the elements of the claimed invention are known in the art is insufficient to establish obviousness. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to

those of ordinary skill in the art." *In re Kotzab,* 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); "[t]he prior art explicitly suggested the substitution that is the difference between the claimed invention and the prior art, and presented preliminary evidence suggesting that the method could be used to make proteins." In re O'Farrell, 853 F.2d 894, 901 (1988); "It is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor." Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934 (1990); prior art must offer "suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior art." In re Vaeck, 947 F.2d 488, 496 (1991); "Knowledge in the prior art of every element of a patent claim, however, is not of itself sufficient to render claim obvious. The issue is whether substantial evidence supports the judgment (under the clear and convincing evidence standard) that a person having ordinary skill in the art would not have been motivated to replace the developing fluid/sample solution combination of Deutsch with flow provided solely by sample fluid." Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1358 (2003).

As amended, Applicants' claimed invention is directed to a dual-specificity antibody, or antigen binding portion thereof to IL-1α and IL-1β wherein the antibody or antigen binding portion is not fully mouse. Claims 4 as amended and claims 12-14 are directed to a method of making the antibody of the invention wherein the antigen comprises overlapping portions of IL-1α and IL-1β (SEQ ID No.3). Claims 16-30 recite specific aspects of Applicants' invention wherein Applicants' dual-specificity antibody is generated using various techniques. Claims 31 and 89-95 recite specific aspects of Applicants' invention wherein the antibody is fully human, chimeric, CDR grafted or humanized. Applicants teach how to generate antigens to generate dual-specificity antibodies. (see specification as filed and in particular pages 7-11 and pages 47-49).

**Luger et al.** teach a fully mouse monoclonal antibody which cross reacts with IL-1α and IL-1β. Luger et al. do not teach, suggest, or motivate one of skill in the art with respect to:

- use of transgenic mice for the production of human or chimeric antibodies;
- use of SCID mice reconstituted with human peripheral blood lymphocytes for the production of human antibodies;
- use of a mouse treated with lethal total body irradiation, followed by radioprotection with bone marrow cells of a SCID mouse, followed by engraftment with functional human lymphocytes for the production of human antibodies;

- screening of recombinant antibody libraries for the production of antibodies;
- screening of recombinant antibody libraries displayed on the surface of yeast cells for the production of antibodies;
- screening of recombinant antibody libraries displayed on the surface of yeast cells or bacterial cells for the production of antibodies;
- screening of recombinant antibody libraries expressed as RNA-protein fusions for the production of antibodies;
- screening of recombinant antibody libraries for the production of antibodies;
- use of in vitro affinity maturation of a recombinant antibody library prepared from lymphoid cells of an animal previously immunized with the antigen to generate antibodies;
- selection of single cells secreting antibodies that bind antigen for the production of antibodies; method of generating chimeric or CDR-grafted antibodies;
- antibodies that are fully human, chimeric, CDR grafted or humanized.

The references cited by the Examiner in combination with the disclosure of Luger et al., disclose the following:

**Green** discloses the use of transgenic mice that generate human antibodies.

**Nguyen et al.** disclose the use of SCID mice reconstituted with human peripheral blood lymphocytes for the production of human antibodies.

**Reisner et al.** disclose the use of a mouse treated with lethal total body irradiation, followed by radioprotection with bone marrow cells of a SCID mouse, followed by engraftment with functional human lymphocytes for the production of human antibodies.

**Barbas et al.** disclose the use of combinatorial (recombinant) antibody libraries on phage surfaces to generate antibodies in vitro.

**WO 99/36569** discloses the use of recombinant antibody libraries displayed on yeast cell surfaces to generate antibodies in vitro.

**WO 98/49286** discloses the use of recombinant antibody libraries displayed on yeast cell surfaces or bacterial cells to generate antibodies in vitro.

**WO 98/31700** discloses the use of recombinant antibody libraries expressed as RNA-protein fusions to generate antibodies in vitro.

**Dower et al.** disclose the use of recombinant antibody libraries to generate antibodies in vitro.

**Salfeld et al.** disclose the use of in vitro affinity maturation of a recombinant antibody library prepared from lymphoid cells of an animal previously immunized with the antigen to generate TNFα antibodies;

**Babcock et al.** disclose the method of isolating single cells secreting antibodies that bind antigen to generate monoclonal antibodies.

**Knappik et al.** disclose the method of generating chimeric or CDR-grafted antibodies.

None of the above-cited references teach, suggest, motivate one skilled in the art, Applicants' dual-specificity antibody capable of binding IL-1α and IL-1β, or method of making the same.

In In re Dembiczak, 175 F.3d 994, 999 (1999), the court stated that "evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, although "the suggestion more often comes from the teachings of the pertinent references." The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." Applicants' also draw the Examiner's attention to a recent decision of the U.S. Court of Appeals for the Federal Circuit, In re Beasley, (Serial No. 07/636,839), 2004 U.S. App LEXIS 25055, decided December 7, 2004. Although this case is nonprecedential, nevertheless, it is instructive concerning the substantial evidence requirement for motivation to combine references. For the Examiner's convenience, a copy of the case is attached as **Exhibit A.**

In the present rejection to Applicants' claimed invention, the Examiner asserts that one of ordinary skill in the art would have been reasonably expected to combine the teaching of Luger et al. with those of the other references cited to produce Applicants' antibodies. The Examiner has provided a multitude of references, but failed to show "evidence" of teaching, suggestion or motivation in the references to combine them and arrive at Applicants' invention. The Examiner makes a broad conclusory statement that one of ordinary skill in the art would expect to be able to produce a superior monoclonal antibody for use in inhibiting IL-1 in inflammation. The Examiner further asserts that "Luger et al. further teaches that that IL-1 is involved in inflammatory disease (pp. 346 and 354) and states that this involvement is the rationale for developing the antibody and would be useful to investigate the role of IL-1 during inflammatory disease (abstract, p. 346).

Like the Board in Dembiczak, the Examiner has combined the cited references one by one, and analyzed them limitation-by-limitation without demonstrating how and where the references teach, suggest, or motivate that they should be or could be combined to arrive at Applicants' invention. Applicants maintain that the disclosure of IL-1 as "a molecule involved in inflammation", combined with a multitude of references disclosing "how to make antibodies with improved characteristics" is NOT a

clear and particular teaching, suggestion, nor does it provide motivation to one of skill in the art to make or to use the anti- IL-1α / β dual-specificity antibody of the present invention.

Although Luger et al. discloses IL-1 is involved in inflammation, they maintain that the role of IL-1 in inflammatory disease needs to be investigated. Luger et al. propose using their mouse monoclonal antibody to investigate the role of IL-1 in inflammatory disease. Any motivation provided by the Luger reference is to investigate the role of IL-1 in inflammation. The reference makes no mention of treating IL-1 mediated diseases or inflammatory diseases with any particular agent, including an antibody capable of inhibiting IL-1. Suggested use of a mouse monoclonal antibody as described by Luger et al., to investigate the role of IL-1 in inflammation is not proper or sufficient evidentiary motivation to generate a dual-specificity antibody capable of binding IL-1α and IL-1β, that is not fully murine as claimed in the present invention to treat inflammatory disease.

Even assuming, *in arguendo*, that Luger et al., provide some suggestion that IL-1 may be useful as a therapeutic target for treatment of inflammatory disease ( to which Applicants' maintain they do not), such suggestion does not provide proper motivation to generate dual-specificity antibody, capable of binding IL-1α and IL-1β.

In Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc. 381 F.3d 1371,1377 (2004), the court held that the invention, a combination of known methods to arrive at a separate treatment of arrhythmias, was non-obvious, because the mere "Recognition of the problem of treating complex heart arrhythmias does not render obvious the eventual solution. Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease (for example, the disease of multiple forms of heart irregularity), and the motivation to create a particular cure." For the Examiner's convenience, a copy of the case is attached as **Exhibit B**.

Like Cardiac Pacemakers, in the present case the identification of a role for the target, IL-1, in inflammatory disease serves as recognition of a problem, namely IL-1 mediated disease. The cited art suggests, at most, using a murine anti IL-1 antibody to explore the role of IL-1 in disease. None of the cited art, singularly or in combination, provides any suggestion or motivation (1) that IL-1 is a potential therapeutic target; (2) targeting IL-1 will be beneficial in treating inflammatory disease; (3) an anti IL-1 antibody is the preferred therapeutic target; (4) that the antibody is a dual-specific antibody to IL-1α and IL-1β; (5) and that the antibody is not fully murine.

In Ruiz v. A.B. Chance Co., 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004), the patent claimed underpinning a slumping building foundation using a screw anchor attached to the foundation by a metal bracket. One prior art reference taught a screw anchor with a concrete bracket, and a second prior art reference disclosed a pier anchor with a metal bracket. The court found motivation to combine the

references to arrive at the claimed invention in the "nature of the problem to be solved" because each reference was directed "to precisely the same problem of underpinning slumping foundations." *Id.* at 1276, 69 USPQ2d at 1690.

Unlike Ruiz, in the present case the cited references do not identify the problem to be solved. As stated supra, Luger et al. discloses IL-1 is involved in inflammation, and they maintain that the role of IL-1 in inflammatory disease needs to be investigated. The reference makes no mention of treating IL-1 mediated diseases or inflammatory diseases with any particular agent, including an antibody capable of inhibiting IL-1. The rest of the references cited disclose techniques for generating antibodies, but make no mention of treating IL-1 mediated diseases or inflammatory diseases with any particular agent. Thus, unlike Ruiz in the present case the cited art do not suggest, teach or provide any motivation to combine the references to arrive at Applicants' invention.

In conclusion, Applicants assert that the Examiner fails to provide the requisite "*clear and particular showing*" of any suggestion or motivation to combine the cited references. The combination of the cited art is made by the Examiner, upon guidance, direction, and motivation to do so, by Applicants' present invention. This is hindsight reconstruction and is impermissible as a basis for rejection under 35 USC §103.

Because the cited art fails to satisfy the criteria necessary to establish or to sustain rejection of claims 1-4, 9, 12-31 and 89-95 as obvious under 35 USC §103(a). In view of the foregoing remarks, Applicants respectfully request withdrawal of the rejection of claims 1-4, 9, 12-31 and 89-95 under 35 USC §103(a).

***Rejections under 35 USC §112, first paragraph***

In the Office action at page 11, paragraph 14-15, claims 1-4, 12-31 and 89-95 are rejected under 35 USC § 112, first paragraph as lacking enablement commensurate with the scope of the claims. The Examiner asserts that the specification, while being enabling for not fully mouse versions of the antibody characterized by Luger et al. and Kock et al. (J. Exp Med., 1986, vol. 163, no. 2, pp. 463-468), as well as those generated by SEQ ID No 3, does not reasonably provide enablement for all dual-specificity antibodies and means of making them. Applicants respectfully disagree.

Claims 1-3 are directed to a dual-specificity antibody, or antigen-binding portion thereof, that specifically binds interleukin-1$\alpha$ and interleukin-1$\beta$, wherein said dual-specificity antibody is not a fully mouse antibody. Applicants respectfully draw the Examiner's attention to the fact that claims 1-3 are not limited by any method of making the antibody. Further, in the Office action at page 11, the Examiner has acknowledged that Applicants' not fully mouse dual-specificity antibody is enabled. The Examiner also

acknowledges that the method of generating such dual-specificity antibodies by using an antigen comprising SEQ ID No 3 is enabled.

Notwithstanding Applicant's traverse, and without in any way acquiescing to the reasons for the present rejection, Applicants have amended claim 4 such that the antigen provided in the method comprises the amino acid sequence TKGGQDITDFQILENQ (SEQ ID NO: 3). Applicants have canceled claims 9 and 10. These amendments are made solely to advance examination of the present application to allowance. This amendment is supported throughout the specification as filed, and no new matter is added. Applicants reserve the right to prosecute the original subject matter in a later-filed continuation application, which properly claims the benefit of this application.

In view of the foregoing remarks, Applicants respectfully request the withdrawal of the rejection to claims 1-4, 12-31 and 89-95 under 37 USC § 112, first paragraph.

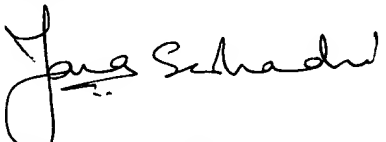
***Allowable Subject Matter***

Applicants acknowledge Examiner's indication that Claim 10 would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims. The subject matter of claim 10, acknowledged by the Examiner as being allowable, is included in claim 4 as amended. Consequently, Applicants have canceled claim 10.

***Conclusion***

In view of the foregoing remarks, Applicants believe that all objections and rejections set forth in the Office Action of 02 August 2004 have been avoided or overcome, and consequently the application is in condition for allowance. Reconsideration and removal of the rejections, and allowance of the pending amended claims are, therefore, respectfully requested.

Respectfully submitted,



Tara Seshadri, Ph.D.
Registration No. 48,591
Agent for Applicants

Exhibit B


6 of 100 DOCUMENTS

**IN RE BRUCE BEASLEY**

**04-1225**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

***2004 U.S. App. LEXIS 25055***

**December 7, 2004, Decided**

**NOTICE:** [*1] THIS DECISION WAS ISSUED AS UNPUBLISHED OR NONPRECEDENTIAL AND MAY NOT BE CITED AS PRECEDENT. PLEASE REFER TO THE RULES OF THE FEDERAL CIRCUIT COURT OF APPEALS FOR RULES GOVERNING CITATION TO UNPUBLISHED OR NONPRECEDENTIAL OPINIONS OR ORDERS.

**PRIOR HISTORY:** (Serial No. 07/636,839).

**DISPOSITION:** Vacated and remanded.

**LexisNexis(R) Headnotes**

**JUDGES:** Before LOURIE, Circuit Judge, ARCHER, Senior Circuit Judge, and DYK, Circuit Judge. Opinion for the court filed by Circuit Judge LOURIE. Dissenting opinion filed by Circuit Judge DYK.

**OPINIONBY:** LOURIE

**OPINION:** LOURIE, Circuit Judge.

Bruce Beasley appeals from the decision of the United States Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences affirming the rejection of claims 1-6 of U.S. Patent Application 07/636,839 as obvious under *35 U.S.C. § 103. Ex parte Beasley, 2002 Pat. App. LEXIS 329, Appeal No. 2001-2202, Paper No. 38 (B. P.A.I. Aug. 29, 2002)* ("Decision on Appeal"); Ex parte Beasley, Appeal No. 2001-2202, Paper No. 40 (B. P.A.I. Oct. 27, 2003) ("Decision on Request for Rehearing"). Because the Board's key factual findings relating to its obviousness analysis are not supported by substantial evidence, the Board erred in concluding that the claims would have been obvious [*2] as a matter of law. We accordingly vacate and remand.

BACKGROUND

On January 2, 1991, Beasley filed U.S. Patent Application 07/636,839 directed to the generation of images or markings on a video display screen using a light pen, so as to point to or otherwise indicate information of interest. Representative claim 1 recites:

> 1. In a system for forming an image on a display screen scanned in frames by a beam:
>
> a light pen movable relative to the screen and having a light sensing element for providing a signal when the position of the light pen coincides with the position of the beam,
>
> a memory having a plurality of addressable storage locations, means for mapping the display screen into the memory on a point-by-point basis by sequentially addressing the memory locations in synchronization with the position of the beam to provide a one-to-one correspondence between the memory locations and the points on the screen,
>
> means responsive to the signal from the light pen for writing data into the memory at locations corresponding to the position of the light pen on the screen during successive frames,
>
> means for reading the data out of the memory locations as they are addressed, [*3] and
>
> means responsive to the data read out of the memory for producing an image

> corresponding to the points where the light pen is positioned during successive frames.

(emphases and paragraphing added).

Previously, the '839 application had been the subject of an appeal to this court, which affirmed the rejection of claims 1-6 under *35 U.S.C. § § 102* and *103* in view of *U.S. Patent 3,832,485* ("Pieters"). *In re Beasley, 1999 U.S. App. LEXIS 16695, No. 99-1055, 1999 WL 515480 (Fed. Cir. July 20, 1999)* (nonprecedential) ("Beasley I"). n1 Beasley thereafter filed a Continued Prosecution Application, in which he amended independent claims 1 and 4 to specifically include the feature of "mapping the display screen into the memory on a point-by-point basis ... to provide a one-to-one correspondence" between the memory locations and the points on the screen (hereinafter referred to as the "point-by-point mapping limitation"). n2

> n1 In Beasley I, claims 1, 3, 4, and 6 had been rejected as being anticipated by Pieters, and claims 2 and 5 had been rejected as being obvious in view of the same. *Beasley I, 1999 U.S. App. LEXIS 16695, 1999 WL 515480 at **1*. Pieters is directed to an apparatus for creating delineations on images using, inter alia, a light pen. Pieters, abstract. **[*4]**

> n2 In the prior appeal, Beasley argued that the point-by-point mapping limitation was to be read into independent claims 1 and 4, in an attempt to avoid anticipation by Pieters. The court in Beasley I concluded that the language of the claims was not sufficiently narrow to require this limitation to be read therein, and consequently affirmed the anticipation rejection. *Beasley I, 1999 U.S. App. LEXIS 16695, 1999 WL 515480 at **3*. After amending the claims to expressly recite the point-by-point mapping limitation, Beasley is now before us again. Although the point-by-point mapping limitation is cast in means-plus-function form, see *35 U.S.C. § 112, P6 (2000)*, the parties do not dispute whether any of the cited references discloses an equivalent structure. Accordingly, we need not identify or consider the structures in Beasley's application that correspond to that function.

Observing that Pieters, by itself, did not disclose the point-by-point mapping limitation, the examiner rejected the amended claims for obviousness under *§ 103* in view of Pieters combined with either one **[*5]** of *U.S. Patent 3,973,245* ("Belser") or *U.S. Patent 4,847,604* ("Doyle"). n3 The examiner cited Belser and Doyle as each disclosing "a conventional bit map memory mapping a display screen into the memory on a point by point basis," and that "it would have been obvious to one of ordinary skill in the art to substitute Belser's [or Doyle's] bit map memory" for the content addressable memory ("CAM") used in Pieters. Jan. 7, 2000 Office Action at 2-3. A skilled artisan would have been motivated to make such a combination, alleged the examiner, "because image data stored in the bit map format can be read out rapidly." Id.

> n3 Belser concerns a method and apparatus for "converting information in coded form into a dot matrix or raster form," Belser, col. 2, ll. 22-24, and presents in considerable detail an algorithm for reformatting data. Belser, col. 5, l. 23 through col. 9, l. 20. Doyle is directed to a system that allows a user to point to a feature on an image and cause descriptive information (e.g., text or a magnified view) to appear. Doyle, col. 11, l. 13 through col. 12, l. 18.

**[*6]**

Beasley responded that the examiner had failed to establish a prima facie case of obviousness because replacing the CAM in Pieters with the memories in Belser and Doyle would require "a complete restructuring" of the system shown in Pieters, which was "not within the purview of obviousness." Apr. 6, 2000 Resp. to Office Action at 2. Arguing that the cited references failed to provide any motivation for the combination, Beasley stressed that the examiner's suggestion for the substitution "appeared to be based entirely on applicant's own disclosure" in an attempt to "piece together" the prior art so as to render the claimed invention obvious. Id. Beasley criticized the rationale proffered by the examiner--that "data stored in a bit map format can be read out rapidly"--as "falling far short of the necessary motivation for the combination." Id.

The examiner rejected Beasley's arguments in a final office action, by repeating the substance of the Jan. 7, 2000 Office Action, and by further alleging that it was "well known in [the] computer display art to substitute a bit map memory for a conventional memory such as the memory used by Pieters." Jun. 14, 2000 Office Action **[*7]** at 4. Insisting that the "advantage of using ... bit map memory over ... conventional memory [was] well

recognized," the examiner listed three advantages: (1) increasing the display rate; (2) ensuring proper correlation of image locations with display locations; and (3) minimizing data processing and storage requirements. Id. In view of those "well recognized" advantages, reasoned the examiner, "it would have been obvious to one of ordinary skill" to make the substitution. Id. at 5.

Beasley appealed the final rejection to the Board, reiterating his arguments against obviousness. The Board agreed with the examiner's reasoning and affirmed n4 the rejection of claims 1-6. n5 Decision on Appeal at 8. The Board found that the cited references suggested to skilled artisans "that if more rapid readout of image data is desired, the bit map memory, rather than the CAM of Pieters, should be employed." Id. at 5-6. With respect to Beasley's restructuring argument, the Board stated that "the artisan skilled in the image display and memory arts would have been well aware of the restructuring" involved when making the substitution. Id. at 6. Disagreeing with Beasley that the **[*8]** examiner's proposed substitution of one memory type for another was "unsupported," the Board reasoned that the "artisan would clearly have understood, from the applied references, the different types of memories available (CAM versus bit map), and their comparative advantages, and would have chosen implementation of one over the other for the advantages sought." Id. Concluding that the examiner established a prima facie case of obviousness, the Board sustained the rejection of claims 1-6.

n4 To the extent the Board adopted the examiner's position as its own, we shall refer to the examiner's findings and conclusions as those of the Board. See *In re Paulsen, 30 F.3d 1475, 1478 n.6 (Fed. Cir. 1994).*

n5 Our discussion will focus on independent claim 1, and, in particular, the point-by-point mapping limitation. The only other independent claim is claim 4, which is directed to a method, but is otherwise similar to independent claim 1 in all material respects. Since Beasley has not made separate patentability arguments for claim 4, or for any of the dependent claims, those claims will stand or fall together with claim 1. See *In re Kaslow, 707 F.2d 1366, 1376 (Fed. Cir. 1983).*

**[*9]**

Beasley filed a request for reconsideration, which the Board denied. Decision on Request for Rehearing at 5. Beasley timely appealed the Board's decision to this court, and we have jurisdiction pursuant to *28 U.S.C. § 1295(a)(4)(A).*

DISCUSSION

A claimed invention may be found to have been obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *35 U.S.C. § 103(a) (2000).* Whether an invention would have been obvious under *§ 103* is a question of law based on underlying findings of fact. *In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000).* We review the Board's legal conclusion of obviousness de novo, and its underlying factual determinations for substantial evidence. *In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000).* Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id. at 1312* (quoting **[*10]** *Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 83 L. Ed. 126, 59 S. Ct. 206 (1938)).*

On appeal, Beasley urges reversal on the basis that the record does not support the Board's determination that the examiner established a prima facie case of obviousness. For a prima facie case of obviousness to exist, there must be "some objective teaching in the prior art or ... knowledge generally available to one of ordinary skill in the art [that] would lead that individual to combine the relevant teachings of the references." *In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988).* "The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved." *Kotzab, 217 F.3d at 1370.*

The presence or absence of a motivation to combine references is a question of fact, *In re Dembiczak, 175 F.3d 994, 1000 (Fed. Cir. 1999)*, which is evaluated under the substantial evidence standard. *Gartside, 203 F.3d at 1316.* Beasley contends that we have before us a case of impermissible hindsight reconstruction, **[*11]** in which the examiner's finding of a motivation to substitute the memory used in either Belser or Doyle for the CAM in Pieters rests on generalized statements of advantages without regard to the desirability or the feasibility of modifying Pieters. Given the "subtle but powerful attraction of a hindsight-based obviousness analysis," we require a "rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *Dembiczak, 175 F.3d at 999.* This is consonant with the obligation of the Board to develop an evidentiary basis for its factual findings to allow for judicial review under the substantial evidence standard that is both deferential and meaningful. See *In re Lee, 277 F.3d 1338, 1344 (Fed. Cir. 2002).*

In evaluating the Board's finding of motivation, we look to the record, for "all of the relevant information upon which the Board relied in rendering its decision." *Gartside, 203 F.3d at 1314*. "That record, when before us, is closed, in that the Board's decision must be justified within the four corners of that record." Id. For the purposes of the present appeal, the record indicates **[*12]** that there have been no less than five occasions, since the filing of the Continued Prosecution Application with the amended claims, on which the Board and the examiner have had the opportunity to develop a factual record that establishes substantial evidence of a motivation to combine Pieters with either Belser or Doyle. They failed to do so in each instance. Our review of (1) the Jan. 7, 2000 Office Action; (2) the Jun. 14, 2000 Office Action; (3) the Feb. 13, 2001 Examiner's Answer; (4) the Decision on Appeal; and (5) the Decision on Request for Rehearing reveals that the assertions pertaining to the advantages of one type of memory over another that had been advanced by the examiner and the Board for the express purpose of showing motivation for the proposed substitution have been set forth without any supporting citations to relevant portions of either Pieters, Belser, Doyle, or any other authority.

For example, the examiner's allegation in the Jan. 7, 2000 Office Action that "image data stored in the bit map format can be read out rapidly" has been repeated axiomatically throughout the record in justifying the replacement of the CAM in Pieters. Neither the Board nor **[*13]** the examiner has identified in the record any source of information--either from the references cited or otherwise--from which they base their comparison of the relative speed advantages of "bit map memories" over CAMs. Similarly, the assertion in the Jun. 14, 2000 Office Action that the "advantage of using ... bit map memory over ... conventional memory is well recognized" appears unaccompanied by any indication of its origins. n6

> n6 While the abstract of Doyle was cited for the proposition that the use of "bit map memory" ensures proper correlation of image locations with display locations, and minimizes data processing and storage requirements, a closer inspection of Doyle reveals that these "advantages" arise out of a specific arrangement for encoding image information, rather than from any intrinsic characteristic of "bit map memories" in general. Doyle, col. 4, ll. 15-19 ("The advantages ... stem from encoding information about a video image as a pixel bit map and a color map in which the addresses or indices of the color map are correlated with the addresses or pointers to strings of descriptive information about predefined features of the video image.").

**[*14]**

In adopting the examiner's position, the Board made no effort to substantiate the examiner's assertions by invoking any identifiable authority. Instead, the Board relied on the examiner's and its own knowledge as skilled artisans. For example, the Board claimed that "the secondary references" suggested to skilled artisans "that if more rapid readout of image data is desired, the bit map memory, rather than the CAM of Pieters, should be employed." Decision on Appeal at 5-6. Similarly, in dismissing Beasley's restructuring argument, the Board alleged that a skilled artisan would have been "well aware" of the restructuring involved. Id. at 6. Under the MPEP provisions n7 in effect at the time, such generalized claims of what "the secondary references" teach and of what the skilled artisan would have been "well aware" fail to satisfy the level of specificity that is required. Cf. *Kotzab, 217 F.3d at 1371* ("Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed."). The MPEP provides guidelines for relying on official notice and **[*15]** personal knowledge, which the examiner did not follow in this case:

> The rationale supporting an obviousness rejection may be based on common knowledge in the art or "well-known" prior art. The examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being "well-known" in the art. *In re Ahlert, 57 C.C.P.A. 1023, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970)* ...
>
> ...
>
> When a rejection is based on facts within the personal knowledge of the examiner, the data should be stated as specifically as possible, and the facts must be supported, when called for by the applicant, by an affidavit from the examiner. Such an affidavit is subject to contradiction or explanation by the affidavits of the applicant and other persons. See *37 CFR 1.104(d)(2)*.
>
> ...
>
> For further views on official notice, see *In re Ahlert, 57 C.C.P.A. 1023, 424*

> *F.2d 1088, 1091, 165 USPQ 418, 420-421 (CCPA 1970)* ("Assertions of technical facts in areas of esoteric technology must always be supported by citation of some reference work" and "allegations concerning specific 'knowledge' **[*16]** of the prior art, which might be peculiar to a particular art should also be supported." ...

MPEP § 2144.03 (7th ed. 1998) (emphases added); see also MPEP § 2144.03 (7th ed., rev. 1, 2000). Certainly, the relative speed advantages of CAMs vis-a-vis "bitmap memories" and the feasibility of substituting one for the other can hardly be described as a fact that is of "instant and unquestionable demonstration" for the purpose of taking official notice unsupported by any citation.

> n7 The Manual of Patent Examining Procedure ("MPEP") is commonly relied upon by patent examiners on procedural matters. *Litton Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1439 (Fed. Cir. 1984).* "While the MPEP does not have the force of law, it is entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith." *Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n. 10 (Fed. Cir. 1995).*

The record reflects that the examiner and the **[*17]** Board have managed to find motivation for substituting one type of memory for another without providing a citation of any relevant, identifiable source of information justifying such substitution. The statements made by the Examiner, upon which the Board relied, amount to no more than conclusory statements of generalized advantages and convenient assumptions about skilled artisans. At least under the MPEP then in effect, such statements and assumptions are inadequate to support a finding of motivation, which is a factual question that cannot be resolved on "subjective belief and unknown authority." *Lee, 277 F.3d at 1344.* Under such circumstances, with respect to core factual findings, "the Board must point to some concrete evidence in the record in support" of them, rather than relying on its assessment of what is "well recognized" or what a skilled artisan would be "well aware." *In re Zurko, 258 F.3d 1379, 1385-86 (Fed. Cir. 2001).* "To hold otherwise would render the process of appellate review for substantial evidence on the record a meaningless exercise." *Id. at 1386* (citing *Baltimore & Ohio R.R. Co. v. Aberdeen & Rockfish R.R. Co., 393 U.S. 87, 91-92, 21 L. Ed. 2d 219, 89 S. Ct. 280 (1968)).* **[*18]**

The PTO, perhaps realizing the deficiencies in the record in this regard, provides numerous citations in its brief to specific passages in Pieters, Belser, and Doyle in a valiant attempt to muster substantiation for the Board's findings. We cannot consider such post hoc attempts at bolstering the record in our review for substantial evidence. *Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168, 9 L. Ed. 2d 207, 83 S. Ct. 239 (1962)* ("Courts may not accept appellate counsel's post hoc rationalization for agency action."). Our review must be limited to those grounds relied on and articulated by the Board; otherwise, the applicant may be deprived of a fair opportunity to support his position. See *Lee, 277 F.3d at 1345*; see also *SEC v. Chenery Corp., 332 U.S. 194, 196, 91 L. Ed. 1995, 67 S. Ct. 1575 (1947)* ("The court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis.").

CONCLUSION

For the above reasons, we conclude that the Board's determination that Beasley's claimed invention would have been obvious in view of the combination of Pieters with either Belser or Doyle is not **[*19]** supported by substantial evidence. Accordingly, we vacate the Board's decision and remand for further proceedings not inconsistent with this opinion.

**DISSENTBY:** DYK

**DISSENT:** DYK, Circuit Judge, dissenting.

I respectfully dissent. Under our decision in Lee the Board may not rely on common knowledge and common sense in rejecting a claim as obvious. *In re Lee, 277 F.3d 1338, 1344-45 (Fed. Cir. 2002).* But both the examiner and the Board are presumed to be skilled in the art, *id. at 1345*, as the majority recognizes, ante at 8. They may properly rely on that knowledge in making rejections for obviousness, but "when they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record." *Lee, 277 F.3d at 1345.*

That is exactly what the examiner and Board have done here. The patent examiner rejected Beasley's claims as obvious over Pieters in view of either Besler or Doyle, finding a motivation to combine in the fact that "image data stored in the bit map format can be read out rapidly." Jan. 7, 2000 Office Action at 2. The examiner sustained his rejection in the subsequent **[*20]** Office Action and specifically addressed Beasley's argument that there was no motivation to combine. The examiner noted that "the advantage of using the bit map memory over the conventional memory is well recognized" and listed three advantages: (1) increasing the display rate; (2) ensuring proper correlation of image locations with display locations; and (3) minimizing data processing

and storage requirements. June 14, 2000 Office Action at 4. The Board agreed with the reasoning of the examiner and further found that an "artisan skilled in the image display and memory arts would have been well aware of the restructuring and manners of address which would need to be changed in order to substitute one type of memory for another." Ex parte Beasley, Appeal No. 2001-2202, Paper No. 38, at 6 (B. P.A.I. Aug. 29, 2002). I see no error in the Board's reliance on the PTO's own specialized knowledge. The effect is merely to create a prima facie case, and to shift the burden to the patent applicant. Here the applicant did not refute the factual findings of the Board and the patent examiner, but merely offered lawyer argument to contradict the Board's findings. Under these circumstances the **[*21]** application was properly rejected.

With this said, I agree that the MPEP provision in effect at the time is not a model of clarity and can be read as recognizing only a very limited scope for the use of the PTO's expertise. MPEP § 2144.03 (7th ed. 1998). However, the current version appears to allow greater latitude. MPEP § 2144.03 (8th ed., rev. 2, 2004). In future cases, where the PTO has provided us with an interpretation of the new MPEP provisions, we will need to address the extent to which the new version of the MPEP gives the PTO greater scope to rely on its own expert knowledge.

Exhibit B


1 of 100 DOCUMENTS

**CARDIAC PACEMAKERS, INC., GUIDANT SALES CORPORATION, and ELI LILLY AND COMPANY, Plaintiffs-Appellants, and ANNA MIROWSKI, Plaintiff-Appellant, v. ST. JUDE MEDICAL, INC., PACESETTER, INC., and VENTRITEX, INC., Defendants-Cross Appellants.**

**02-1532, 02-1559**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

***381 F.3d 1371; 2004 U.S. App. LEXIS 18386; 72 U.S.P.Q.2D (BNA) 1333***

**August 31, 2004, Decided**

**SUBSEQUENT HISTORY:** Rehearing denied by, Rehearing, en banc, denied by *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 2004 U.S. App. LEXIS 25301 (Fed. Cir., Nov. 2, 2004)*

**PRIOR HISTORY:** **[**1]** Appealed from: United States District Court for the Southern District of Indiana. Judge David F. Hamilton. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 2000 U.S. Dist. LEXIS 17352 (S.D. Ind., Nov. 29, 2000)*
*Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 2002 U.S. Dist. LEXIS 14767 (S.D. Ind., July 5, 2002)*

**DISPOSITION:** AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.

**LexisNexis(R) Headnotes**

**COUNSEL:** Arthur I. Neustadt, Oblon, Spivak, McClelland, Maier & Neustadt, P.C., of Alexandria, Virginia, for plaintiff-appellant Anna Mirowski, argued for plaintiffs-appellants. With him on the brief was Jeffrey B. McIntyre. Of counsel on the brief was Richard R. McDowell, Hill, Fulwider, McDowell, Funk & Matthews, of Indianapolis, Indiana. Also on the brief were J. Michael Jakes and Kara F. Stoll, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, for plaintiffs-appellants Cardiac Pacemakers, Inc., et al.

Denis R. Salmon, Gibson, Dunn & Crutcher LLP, of Palo Alto, California, argued for defendants-cross appellants. With him on the brief was H. Mark Lyon. Also on the brief was Mark A. Perry, of Washington, DC. Of counsel on the brief were Jeffrey M. Olson, Sidley Austin Brown & Wood LLP, of Los Angeles, California, and Michael I. Rackman, Gottlieb, Rackman & Reisman, P.C., of New York, New York.

**JUDGES:** Before NEWMAN, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Circuit Judge.

**OPINIONBY:** NEWMAN

**OPINION:** **[*1373]** NEWMAN, **[**2]** Circuit Judge.

This patent infringement action was brought by Cardiac Pacemakers, Inc., Guidant Sales Corp., Eli Lilly and Company, and Anna Mirowski (collectively "CPI") against St. Jude Medical, Inc., Pacesetter, Inc., and Ventritex, Inc. (collectively "St. Jude"), in the United States District Court for the Southern District of Indiana. n1 The **[*1374]** appeal relates to *United States Patent No. 4,407,288*, entitled "Implantable Heart Stimulator and Stimulation Method," inventors Alois A. Langer, Steve A. Kolenik, Marlin S. Heilman, Mieczyslaw Mirowski, and Morton M. Mower. We affirm in part and modify in part the district court's claim construction, reinstate the jury verdict of validity, and remand for a new trial of infringement and reassessment of damages. We affirm the district court's decision upholding the patent term extension.

n1 *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., NO. IP 96-1718-C H/G, 2000 U.S. Dist. LEXIS 17352 (S.D. Ind. Nov. 29, 2000)*

(Claim Construction); Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., NO. IP 96-1718-*C H/G, 2002 U.S. Dist. LEXIS 14767* (S.D. Ind. July 5, 2002) (Amended Final Judgment).

**[**3]**

THE PATENTED INVENTION

The pumping action of the human heart occurs by electrical stimulation of various parts of the heart muscle, a complex process flowing from the nervous and other bodily systems. Heart arrhythmias result from disturbances in this process, whereby the heart may beat too slowly (bradycardia), too rapidly (tachycardia), or in an erratic, disorganized, or quivering fashion (fibrillation). Arrhythmias may occur in varying degrees. In treating such heart abnormalities it is important to determine the form and degree of arrhythmia present, as well as to identify the section or sections of the heart in which the arrhythmia originates, such as the ventricles or the atria. The treatment must be appropriate to the specific abnormality.

The inventions subject of this lawsuit are implantable cardiac defibrillators (ICDs) that are permanently installed under the skin, and that determine abnormal cardiac activity and treat that activity by delivering electrical shocks to the heart muscle in appropriate strengths. The first successful ICDs were developed in about 1980 by a team led by the late Dr. Mieczyslaw Mirowski, an inventor of the patents in suit. In the district court **[**4]** two patents were in suit, for improved ICDs whereby the ICD evaluates the abnormal heart activity, determines the pattern of electrical stimulation needed to treat the type of arrhythmia exhibited by the heart, delivers the appropriate electrical pulses or shocks, and changes the pulses as necessary for optimum treatment. *United States Patent No. 4,316,472* (the '472 patent) is for an improved ICD whereby the implanted device analyzes the arrhythmia, and the requisite energy levels for electrical shocks to the heart are calculated and externally programmed. Patent No. *4,407,288* (the *'288* patent) is for a further improvement that continuously determines the nature of an arrhythmia as it occurs, and selectively performs multi-mode therapy. Multi-mode therapy includes administering relatively mild pacing shocks to correct mild arrhythmias, intense shocks to correct fibrillation, and shocks appropriate to correct cardioversion, which the district court defined as "the application of non-pacing electrical pulses designed to stimulate sufficient heart tissue to correct an arrhythmia, with energy levels generally below those used for defibrillation." The cardioversion capability is basic to **[**5]** this appeal.

CPI charged St. Jude with infringement of claims 1 and 18 of the '472 patent and claims 4 and 13 of the *'288* patent. The jury found St. Jude liable for infringement of the '472 patent, but not the *'288* patent. The jury found both patents valid, and rejected St. Jude's charge that the *'288* patent is unenforceable for inequitable conduct during patent prosecution. The jury awarded damages of $ 140 million for infringement of the '472 patent.

On post-trial motions the district court granted JMOL in favor of St. Jude on most of the issues on which CPI had prevailed in the jury verdict. The court held that the claims of both the '472 patent and **[*1375]** the *'288* patent are invalid and not infringed, and granted a conditional new trial in the event of reversal on appeal. The court also granted St. Jude's motion for sanctions based on witness misconduct, and awarded partial attorney fees to St. Jude based on Cardiac Pacemakers' failure to comply with certain discovery obligations.

No appeal is taken as to the '472 patent. CPI appeals the judgment of invalidity and non-infringement of the *'288* patent, and requests reinstatement of the jury verdict. St. Jude cross appeals the court's **[**6]** ruling, as a matter of law, that patent term extension was properly granted.

I

VALIDITY

At issue are claims 4 and 13 of the *'288* patent. Claim 4, and claim 1 from which it depends, state:

> 1. A method of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising the steps of:
>
> (a) determining a condition of the heart from among a plurality of conditions of the heart;
>
> (b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition; and
>
> (c) executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.

> 4. The method of claim 1, wherein at least one mode of operation of said implantable heart stimulator includes cardioversion.

Claim 13, and claim 10 from which it depends, state:

> 10. An implantable heart stimulator capable of monitoring and detecting a plurality **[**7]** of arrhythmias, and capable of being programmed to undergo a single or multi-mode of operation corresponding to a respective arrhythmia to treat automatically the detected arrhythmia, said stimulator comprising:
>
> determining means for determining the occurrence of one of a plurality of conditions of the heart;
>
> selecting means responsive to said determining means for selecting at least one mode of operation of said implantable heart stimulator corresponding to a respective one of said plurality of conditions for automatically treating said determined conditions; and
>
> executing means for executing a sequence of events defined by said at least one mode of operation, whereby to treat said determined condition.
>
> 13. The stimulator of claim 10, wherein said at least one mode of operation includes cardioversion.

Granting judgment of invalidity as a matter of law, the district court ruled that Claims 4 and 13 are invalid on the ground of obviousness and for failure to disclose the best mode of making and using the invention.

Obviousness

In review of a jury verdict on the ground of obviousness, the underlying findings of fact, whether explicit or presumed as necessary to **[**8]** support the verdict, are reviewed for substantial evidentiary support; and the ultimate question of obviousness is reviewed for correctness in law, based on the factual premises. See *Hewlett-Packard Co. v. Mustek Systems, Inc., 340 F.3d 1314, 1319* **[*1376]** *(Fed. Cir. 2003); LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353 (Fed. Cir. 2001).* These standards are applied by the district court upon motion for judgment as a matter of law, and again by the appellate court upon grant or denial of that motion. *Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc., 248 F.3d 1303, 1309 (Fed. Cir. 2001)* ("This court reviews a district court's grant of JMOL de novo and reapplies the JMOL standard.") (citing *Markman v. Westview Instruments, Inc., 52 F.3d 967, 975 (Fed. Cir. 1995)* (en banc), aff'd, *517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996)).*

CPI argues that the jury verdict must be upheld because there was substantial evidence at trial whereby a reasonable jury could have sustained the validity of the patent on the ground of obviousness, pointing out that issued patents can only be proved invalid **[**9]** by clear and convincing evidence. See, e.g., *Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 988 (Fed. Cir. 1989)* (reviewing the verdict in light of the burden of proof).

At the trial each side explained what the cited references taught, as well as the general knowledge in this field of technology at the time the invention was made. The jury was instructed that:

> The suggestion [to combine elements from separate references] can be expressly stated in a particular reference or it can be within the knowledge that was generally available to one of ordinary skill in the art.

Jury Instruction No. 46. Prior knowledge in the field of the invention must be supported by tangible teachings of reference materials, and the suggestion to combine references must not be derived by hindsight from knowledge of the invention itself. See *Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1578-79 (Fed. Cir. 1997)* ("However, the record must provide a teaching, suggestion, or reason to substitute computer-controlled valves for the system of hoses in the prior art. The absence of such a suggestion to combine is dispositive in **[**10]** an obviousness determination."); *Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985)* ("When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.").

CPI's witnesses testified that the *'288* invention was not a simple combination of known steps, but a complex solution to a difficult problem, achieved amid skepticism concerning the feasibility of producing a single implantable device that could detect and treat a wide range of heart abnormalities. St. Jude's witnesses disagreed with CPI as to the unobviousness of the combination. Evidence was presented to the jury of a

long-felt but unmet need to achieve multi-mode detection and stimulus capability that included cardioversion. There was evidence that cardioversion was not treatable by existing multi-mode ICD's, and there was evidence of skepticism that such multi-mode treatment could be achieved. The jury found that invalidity of the *'288* patent on the ground of obviousness had not been proved.

The district court, granting St. Jude's motion **[**11]** for judgment as a matter of law, found that each of the elements of claims 4 and 13 was previously known. The court cited references that described implanted cardiac devices that provided multimode therapy, although none included cardioversion therapy. The court found that cardioversion therapy was known, and found that "compelling motivation" to combine therapies in a single implanted device was provided by an article by Haft, wherein **[*1377]** Haft explained that pacing therapy may trigger ventricular fibrillation. The district court found that Haft identified the problem solved by the *'288* patent, and concluded that it would have been obvious to design a pacing device that could defibrillate if necessary. That is, the court found that there was a known need to treat mixtures of arrhythmias, and that it would have been obvious to combine known methods of separate treatment.

Among the cited references, the district court placed weight on a British patent 2,026,870 to Duggan, as providing the motivation to combine treatments of different arrhythmias. Duggan discusses cardioversion achieved by application not of a single large shock, as in the *'288* patent, but by a combination of small pacing **[**12]** shocks delivered simultaneously to multiple sites on the heart. CPI's expert explained that what Duggan taught was a form of pacing and not true cardioversion, and concluded that Duggan does not propose the combination of therapies provided by the *'288* patent, or teach how to achieve a device that produces this combination.

We think that the district court, in granting JMOL, applied an incorrect standard to the ultimate question. Recognition of the problem of treating complex heart arrhythmias does not render obvious the eventual solution. Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease (for example, the disease of multiple forms of heart irregularity), and the motivation to create a particular cure.

There can of course arise situations wherein identification of the problem is itself the invention. But in the case at bar the problem was well-recognized: the problem of treating complex cardiac arrhythmias. The solution of this problem, according to the trial proceedings, had not previously been achieved. It was undisputed that before the work of Dr. Mirowski **[**13]** and his team there was no implantable device that was capable of treating the combination of abnormal arrhythmias including cardioversion. Recognition of an unsolved problem does not render the solution obvious.

Expert witnesses for each side presented opposing opinions as to the unobviousness of the Mirowski invention. St. Jude's expert testified that in his opinion persons of ordinary skill in the relevant field would have been motivated to modify Duggan "if one felt it [cardioversion] would be better accomplished with a single high energy shock." CPI's expert testified that the Duggan reference teaches away from use of high-energy shock because Duggan is concerned only with power consumption in ICDs. St. Jude stressed the obviousness of high energy cardioversion or defibrillation shocks due to the statement in the Haft article that "antitachycardia pacing could induce fibrillation." CPI presented contrary expert opinion, stressing that no reference teaches combining cardioversion with other cardiac therapies in a single device, or states that it is feasible to do so.

It was not disputed that before the *'288* invention this combination of modes of treatment had not been achieved. **[**14]** CPI pointed out that claim 4 requires cardioversion, not defibrillation, and that the Haft article is concerned with fibrillation. The jury heard testimony that defibrillation shocks, not cardioversion shocks, revert fibrillation. The jury also heard testimony that defibrillation energy levels are different from cardioversion energy levels. While the jury also heard testimony that "cardioversion and defibrillation are so similar to practically be the same therapy," other witnesses disputed this position.

**[*1378]** Whether the prior art provides the suggestion or motivation or teaching to select from prior knowledge and combine it in a way that would produce the invention at issue is a question of fact. *Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1348 (Fed. Cir. 2000)*. These issues were extensively explored at the trial, including evidence of the commercial success and the interest of others in licensing the Mirowski inventions. The record contains substantial evidence whereby a reasonable jury could have reached the verdict that it would not have been obvious in March 1981 to provide an ICD that includes cardioversion. In view of this evidentiary support, the district **[**15]** court's grant of JMOL cannot stand. See *Continental Air Lines, Inc. v. Wagner-Morehouse, Inc., 401 F.2d 23, 30 (7th Cir. 1968)* n2 (the jury verdict must be sustained, even if the judge would have reached a different conclusion, if the verdict is supported by substantial evidence). The grant

of JMOL is reversed, and the jury verdict is reinstated that the *'288* patent is not invalid for obviousness.

> n2 We apply the procedural law of the regional circuit in reviewing the procedure underlying the district court's post-trial determinations. See *National Presto Co. v. West Bend Co., 76 F.3d 1185, 1188 n.2 (Fed. Cir. 1996)* ("On procedural matters not unique to the areas that are exclusively assigned to the Federal Circuit, the law of the regional circuit shall be applied.")

Best Mode

St. Jude also presented the defense that the *'288* patent is invalid for failure to set forth the best mode of practicing the invention. The jury found that the patents were not invalid on this ground. **[**16]** On St. Jude's post-trial motion the district court ruled that the best mode requirement was violated, and granted judgment of invalidity as a matter of law. On this question of fact, we review the evidentiary record for substantial evidence supporting the jury verdict.

A best mode violation requires that the inventor knew of and concealed a better mode than was disclosed for making and using the claimed invention. *Randomex, Inc. v. Scopus Corp., 849 F.2d 585, 588 (Fed. Cir. 1988)* ("It is concealment of the best mode of practicing the claimed invention that *section 112 para.1* is designed to prohibit.") (emphasis in original); *Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384-85 (Fed. Cir. 1986)* ("in order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed").

The best mode requirement differs from the enablement requirement, for failure to enable an invention will produce invalidity whether or not the omission was deliberate, whereas invalidity for omission of a better mode than was revealed requires knowledge of and concealment of that **[**17]** better mode. See *In re Gay, 50 C.C.P.A. 725, 309 F.2d 769, 772, 1962 Dec. Comm'r Pat. 737 (CCPA 1962)* (best mode requirement precludes inventors "from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived"). Thus the inventor must disclose the best mode of what he claims as his invention. See also, e.g., *Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1575 (Fed. Cir. 1992)* ("Invalidity for violation of the best mode requires intentional concealment of a better mode than was disclosed . . . . ") The question here raised relates to the best mode obligation with respect to subject matter that is not part of the invention, but that is used in conjunction therewith -- here the **[*1379]** battery for use with these battery-powered ICDs.

St. Jude argued at trial that the inventors were required to include in the patent specification the best battery known to them at the time the patent application was filed. The inventors had asked Honeywell to develop an improved battery for use in these cardiac devices; Honeywell did so, and about four months before the *'288* application was **[**18]** filed Honeywell published an article at the Power Sources Conference, describing the battery that it developed. The inventors testified that a battery was not part of their invention, that the Honeywell and other batteries for ICDs were known when the *'288* application was filed, that various known batteries were usable in their device, that in the evolving battery art other batteries were being developed, and that they actually chose a different battery for their commercial device. The inventors stressed that their invention was not about batteries, that there was no intent to conceal the Honeywell or any battery, and that it was not concealed. St. Jude argued that a battery was necessary to operate the device, that the Honeywell battery should have been mentioned, and that not mentioning it amounted to culpable concealment. The jury found in favor of CPI on this question.

The district court, reversing the jury verdict, held that the inventors were required to include the Honeywell battery in the patent specification, since it was the best battery then known to them. The court deemed it insufficient that Honeywell had publicly described and published the battery, and found that Honeywell's **[**19]** publication was in "a forum for battery specialists, not for cardiologists and inventors of ICDs." The court held that failure to include the Honeywell battery in the specification invalidated the patent on best mode grounds.

CPI states that the district court erred in law, pointing out that the invention is not about batteries, that the Honeywell battery was known, and that there was no evidence or basis for inference of intent to conceal the battery. The obligation to disclose the best mode relates to the invention that is described and claimed. See *Engel Industries, Inc. v. Lockformer Co., 946 F.2d 1528, 1532 (Fed. Cir. 1991)* ("The best mode inquiry is directed to what the applicant regards as the invention, which in turn is measured by the claims.") Subject matter that is not part of the invention that is claimed need not be included in the specification, and thus is not subject to the best mode requirement. As explained in *Engel, 946 F.2d at 1532-33*, "the reasons are pragmatic: the disclosure would be boundless, and the pitfalls endless."

There was evidence before the jury that persons knowledgeable in the field of the invention would know the **[**20]** sources of batteries for pacemakers and related devices. There was no evidence of concealment, and the jury had evidence that the Honeywell battery was published in a publication for battery specialists. There was substantial evidence whereby a reasonable jury could have found that the best mode requirement had not been violated. The grant of JMOL on this issue is reversed, and the jury verdict is reinstated.

The Conditional New Trial

On the validity issues, the district court granted a new trial in the event of our reversal of the grant of judgment as a matter of law. We review the grant of a new trial in accordance with Seventh Circuit standards, see n.2 supra, as stated in, e.g., *Billy-Bob Teeth, Inc. v. Novelty, Inc., 329 F.3d 586, 590-91 (7th Cir. 2003)* ("We review a grant of a new trial for abuse of **[*1380]** discretion. A new trial may be granted only when the verdict is against the manifest weight of the evidence.")

The jury verdicts on the issues of obviousness and best mode were not against the manifest weight of the evidence. See *Continental Air Lines, 401 F.2d at 30* ("If the evidence in the record, viewed from the standpoint of **[**21]** the successful party, is sufficient to support the jury verdict, a new trial is not warranted merely because the jury could have reached a different result. Neither the trial court nor this Court may substitute its judgment for that of the jury on disputed issues of fact.") (quoting *Gebhardt v. Wilson Freight Forwarding Co., 348 F.2d 129, 133 (3d Cir. 1965)*). Further, there was no issue of prejudicial procedural error or incorrect instruction of law. In these circumstances the conditional grant of a new trial exceeded the court's discretionary authority, and is vacated.

INFRINGEMENT

The jury found that claims 4 and 13 of the *'288* patent are not infringed. Only the judgment as to claim 4, the method claim, is appealed.

CPI argues that the district court incorrectly construed claim 4 as being in the form of *35 U.S.C. § 112 P6*, and thereby incorrectly instructed the jury with respect to infringement. CPI argues that on the correct claim construction, the undisputed facts establish that the accused devices infringe claim 4. St. Jude disagrees, and also states that the misconduct of one of CPI's expert witnesses so tainted the issue of infringement **[**22]** that in all events a new trial of infringement is required if this court modifies the claim construction. The district court sustained the verdict of non-infringement, and granted a conditional new trial on the ground of witness misconduct.

Procedural Matters

St. Jude states that CPI failed to preserve a right to appeal the claim construction, because CPI did not make formal objection when the jury was instructed on the claim construction. CPI responds that the claim construction was decided at the Markman hearing, and was not a proper subject of trial objection under *Rule 51*. St. Jude counters that all objections must be raised at the specified times during a jury trial, or they are waived. Thus St. Jude states that CPI has no right to appellate review of the claim construction that was decided at the Markman hearing and on which the jury was instructed and the trial conducted.

*Rule 51* prevents a party from assigning error to an incorrect jury instruction that could have been corrected if the error had been timely raised. A party must warn the court and the opposing party that there has been an error of law. Here, the asserted error was the decision of the Markman **[**23]** hearing, held well before trial. The district court's construction of the claims was resolved in that decision, and was the subject of a written decision issued some six months before trial. The jury was instructed in accordance with that decision.

CPI points out that the issues of claim construction had been fully argued and briefed at the Markman hearing, and that its disagreement concerning *§ 112 P6* was well known to the district court during that hearing. CPI refers to the "futility" exception, recognized by the Seventh Circuit in *Chestnut v. Hall, 284 F.3d 816, 820 (7th Cir. 2002)* ("A party may be excused from complying with the formalities of *Rule 51* where: (1) the party's position has been previously made clear to the court; and (2) further objection would be unavailing and futile. ") (citing *Carter v. Chicago* **[*1381]** *Police Officers M.L., 165 F.3d 1071, 1078 (7th Cir. 1998))*. Cf. *Ecolab Inc. v. Paraclipse, Inc., 285 F.3d 1362, 1369-70 (Fed. Cir. 2002)* (applying regional circuit law to *rule 51* and the futility exception).

When the claim construction is resolved pre-trial, and the patentee presented the same position in the **[**24]** Markman proceeding as is now pressed, a further objection to the district court's pre-trial ruling may indeed have been not only futile but unnecessary. In this case the court's claim construction resulted from a hearing at which all parties' positions were presented, and the applicability of *§ 112 P6* to the claims was extensively argued. The issue was complex, and it was fully litigated to the court, who announced its decision before the jury was instructed. Objection under *Rule 51* was not required to preserve the right to appeal the Markman ruling.

Claim Construction

CPI argues that the district court incorrectly construed clause (a) of claims 1 and 4:

> (a) determining a condition of the heart from among a plurality of conditions of the heart.

The court held that clause (a) is in the step-plus-function form of *§ 112 P6*. n3 Implementing that holding, the court ruled that clause (a) "is limited to detecting and distinguishing among arrhythmia by analyzing the outputs of rate circuitry and PDF [probability density function] circuitry," the process in the *'288* specification. The jury was instructed that unless a combination of rate output and PDF circuitry **[**25]** or the equivalent thereof was used in the St. Jude device, the claim was not infringed.

> n3 *35 U.S.C. § 112 P6*. An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

CPI states that this claim construction is incorrect, that clause (a) is not in *§ 112 P6* form and is not converted to that form simply because the preamble of the claim states that the invention is "the method comprising the steps of:". See claim 1, ante. CPI states that clause (a) simply recites a step that is part of the claimed method, and that absent the signal "step for" there is a presumption that a step does not invoke *§ 112 P6*. The district court disagreed, stating that if clause (a) were construed as CPI proposes, it would "allow[] CPI **[**26]** to claim all possible methods of detecting heart arrhythmia." Concluding that the patent would thus "sweep[] too broadly," the court ruled that clause (a) covers only the specific procedures in the specification for determining the condition of the heart, and technologic equivalents of those procedures.

CPI is correct that "claiming a step by itself, or even a series of steps, does not implicate *§ 112 P6*," as explained in *O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1582 (Fed. Cir. 1997)*. Thus clause (a) was inappropriately assigned to *§ 112 P6* . However, removal of clause (a) from *§ 112 P6* does not automatically convert it into an open-ended step without limits. A claim limitation is always construed in light of the specification, whatever the form of the claim. See, e.g., *Kinik Co. v. U.S. International Trade Comm'n, 362 F.3d 1359, 1365 (Fed. Cir. 2004)* ("The words of patent claims have the meaning and scope with which they are used in the specification and the prosecution history."); *Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)* ("The best **[*1382]** source for understanding a technical term is the **[**27]** specification from which it arose, informed, as needed, by the prosecution history."); *Grain Processing Corp. v. American Maize Products Co., 840 F.2d 902, 908 (Fed. Cir. 1988)* ("All claims must be construed in light of the specification and the prosecution history.").

CPI argues that upon the correct claim construction the "determining" step is not limited to any particular procedure, because the specification makes clear that various methods may be used to determine the condition of the heart. The specification, after describing the PDF circuitry, states that "conventional logic circuitry" can be used:

> It is also to be noted that conventional logic circuitry can be provided for determining, based on the previously discussed inputs, the existence of various medical conditions, for example, ventricular tachycardia, ventricular fibrillation and super-ventricular tachycardia. Such conventional logic circuitry can be provided either in the dedicated cardiac state evaluation circuit 34, or in one of the processors/controllers to be discussed below.

*'288* patent, col. 10, lines 19-28 (emphasis added). CPI argues that the invention is not based on how **[**28]** the cardiac condition is determined, but on the treatment that is applied to that condition. CPI states that the rate plus PDF method is simply a preferred embodiment, and that this limitation should not be imported into the claim.

We conclude that the district court erred in applying *§ 112 P6*. Method claims necessarily recite the steps of the method, and the preamble words that "the method comprises the steps of" do not automatically convert each ensuing step into the form of *§ 112 P6*. Nor does the preamble usage "steps of" create a presumption that each ensuing step is in step-plus-function form; to the contrary, the absence of the signal "step for" creates the contrary presumption. The district court's claim construction is modified accordingly; the "determining" step must be construed, as for all claim steps, in light of

the specification and the prosecution history. We remand to the district court for that purpose.

Infringement

CPI states that if *§ 112 P6* is eliminated from the claim construction, judgment in favor of CPI is required. St. Jude states that if the claim construction is changed, at a minimum there should be a new trial of infringement.

CPI states that **[**29]** the jury reached the incorrect verdict of non-infringement of the *'288* patent because of the incorrect claim construction. At the trial, on the instruction that only rate-plus-PDF detection circuitry or its technologic equivalent was covered by the claim, the jury found no infringement of the *'288* patent. There was extensive evidence that St. Jude did not use a rate-plus-PDF procedure. CPI did present evidence to try to prove that the St. Jude circuitry is equivalent to PDF circuitry, and St. Jude presented contrary evidence. CPI argues that on the correct claim construction, any method of determining the condition of the heart would literally satisfy clause (a), and that the question of *§ 112 P6* equivalency should not have arisen. CPI argues that we can, and should, find infringement as a matter of law once we correct the district court's claim construction.

St. Jude responds that if we modify the district court's claim construction, as we have, a new trial is required so it can present evidence and argument that were not needed under the district court's original **[*1383]** claim construction, such as whether the now-asserted scope of the claims is supported by the specification. St. Jude **[**30]** points out that it is entitled to jury determination of the question of infringement. We agree. It is well established that when an incorrect jury instruction -- such as an incorrect claim construction -- removes from the jury a basis on which the jury could reasonably have reached a different verdict, the verdict should not stand. See *Texas Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1201 (Fed. Cir. 2002)* (an erroneous instruction on claim interpretation that affects the jury's verdict on infringement is grounds for a new trial); *Ecolab Inc. v. Paraclipse, Inc., 285 F.3d 1362, 1373 (Fed. Cir. 2002)* (same).

CPI is correct that a claim construction limited to *§ 112 P6* equivalency would remove the possibility of finding infringement if the CPI and St. Jude circuitries were not technologically equivalents but nonetheless determined the condition of the heart. We conclude that a new trial of infringement is required, for the question of infringement was not explored on the purportedly less restrictive claim construction that avoids *§ 112 P6*. That question requires findings and conclusion by the trier of fact.

The Sanctions for False Testimony **[**31]**

The district court held that if a new trial of infringement is required, CPI should pay St. Jude's attorney fees for the new trial because of the misconduct of a CPI infringement expert. CPI argues that if the new trial of infringement is based solely on the district court's erroneous claim construction and is unrelated to the false testimony of the witness, n4 the contingent sanction of attorney fees should be vacated.

> n4 The witness had concealed contradictory testimony that he had given in a related case. CPI has paid and is not appealing the sanctions already imposed, for St. Jude's attorney fees and expenses associated with the false testimony.

The new trial here ordered is unrelated to the witness' deception; indeed, the jury rendered a verdict of noninfringement of the *'288* patent despite his contrary testimony. Therefore the conditional sanction is vacated.

DAMAGES

The jury awarded damages of $ 140 million for infringement of the '472 patent. The district court granted JMOL of non-infringement of the **[**32]** '472 patent; that judgment is not appealed. CPI asks that the damages award be applied to the *'288* patent, arguing that the same evidence was presented for both patents without distinction. St. Jude responds that the damages award cannot be shifted to a patent that the jury found not to be infringed, and argues that it is excessive in any event.

We conclude that it is inappropriate to shift the jury's damages award. The damages for infringement of the *'288* patent, should infringement be found on remand, requires determination on remand.

PATENT TERM EXTENSION

St. Jude by cross appeal challenges the district court's ruling that the term of the *'288* patent was properly extended under the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act). The Act permits a patentee to obtain an extension of the patent term if marketing of the patented product was delayed due to federal regulatory review:

> *35 U.S.C. § 156(a)* The term of a patent which claims a product, a method of using a product, or a method of manufacturing **[*1384]** a product shall be extended in accordance with this section from the

> original expiration date of the patent, which shall **[**33]** include any patent term adjustment granted under *section 154(b)*, if --
>
> . . . .
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use;
>
> (5) (A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;
>
> (B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent;

(Emphasis added.)

Questions of statutory interpretation receive plenary review on appeal. *Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003)*; *Hosiden Corp. v. Advanced Display Manufacturers, 85 F.3d 1561, 1567 (Fed. Cir. 1996)*. The question here arises because the **[**34]** CPI device is not the first device covered by the *'288* patent to receive FDA approval. CPI had granted licenses to two other companies for defibrillators, however, term extension was not requested based on the licensees' devices. In CPI's application for extension based on its PRx defibrillator, CPI stated that licenses had been granted for two other defibrillators covered by the *'288* patent, the Ventritex V-100 and the Medtronic PCD, for each of which the licensee had obtained FDA approval. The Patent and Trademark Office and the FDA granted the extension based on the PRx approval period.

The district court held that extensions under *subsection (5)(A)* need not be based on the first FDA-approved medical device covered by the patent, but must be based on " **[*1385]** the first permitted commercial marketing or use of the product" that is the basis of the application. The district court stated that the statute gives patentees a choice "in matching up products and the patents for which they seek extensions."

St. Jude argues that the district court erred, and that CPI's PRx defibrillator cannot be a basis for extension of the term of the *'288* patent, no matter how independent its FDA approval procedure, **[**35]** because the Ventritex and Medtronic ICDs were previously approved and commercialized. CPI responds that when various devices, all requiring separate regulatory approval, are covered by the same patent, it suffices that the particular device on which the application for extension is based is covered by the patent and is subject to regulatory review, and that only one extension per patent is available.

The district court agreed with CPI, and held that *§ 156(a)(5)(A)* does not require that the device on which the extension is based is the first approved product within the claims of the patent. The court stated: "The court should not read into *subparagraph (a)(5)(A)* the limiting requirement that Congress imposed so clearly in writing *subparagraph (a)(5)(B)*, but only for method patents primarily using recombinant DNA technology." The district court relied on the fact that *§ 156(a)(5)(A)* refers to "marketing or use of the product" that the patentee has selected, whereas *subparagraph (a)(5)(B)*, for DNA technology, refers to "the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent." In Brown v. Gardner the Court cautioned **[**36]** that "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *513 U.S. 115, 120, 130 L. Ed. 2d 462, 115 S. Ct. 552 (1994)* (quoting *Russello v. United States, 464 U.S. 16, 23, 78 L. Ed. 2d 17, 104 S. Ct. 296 (1983))*.

St. Jude argues that the comparison between *subparagraphs (a)(5)(B)* and *(a)(5)(A)* is strained, and does not support the distinction drawn by the district court. St. Jude criticizes the weight the court gave to the change in text from "the" to "a," and directs attention to *Fisons PLC v. Quigg, 876 F.2d 99, 100-01 (Fed. Cir. 1989)*, wherein this court held that a drug-patent extension must be based on the first FDA approval of the active ingredient of the patented product because, under the definition in *§ 156(f)(2)*, the active ingredient is the approved "product." Thus in Fisons the court held that subsequent extensions were not available for subsequent products using the same active ingredient that was the basis of the first extension, implementing the principle that only one extension is available **[**37]** per approved product. See *Fisons, 876 F.2d at 100* ("It follows that because Fisons' patented new products containing cromolyn sodium did not qualify as the first permitted commercial marketing or use of the active ingredient cromolyn sodium, extensions of the patent term for the subject patents were not permissible.")

The district court agreed that only one extension was available, but held that the patentee was not required to rely on a licensee's version of the device as the basis for the extension. The legislative history supports this interpretation, for as originally proposed *§ 156(a)* required that extensions "be granted only for the first approved product," H.R. Rep. No. 98-857, pt. 1, at 38 (1984), but that provision was removed from the legislation before enactment. See *Gulf Oil Corp. v. Copp Paving Co., 419 U.S. 186, 200, 42 L. Ed. 2d 378, 95 S. Ct. 392 (1974)* (Congress's failure to enact a proposed version of a statute "strongly militates against a judgment that Congress intended a result that it expressly declined to enact.")

The decision that extension was available based on CPI's PRx defibrillator is affirmed.

Lapse Due to Incorrect Payment of **[**38]** Maintenance Fees

St. Jude also argues that the *'288* patent expired when CPI did not pay the correct maintenance fee, and that although the payment was later corrected and accepted by the Patent and Trademark Office, the patent must be deemed to have expired with the error, at least for purposes of term extension:

> *35 U.S.C. § 156(a)* The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section . . . if --
>
> (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension.

The district court held that, in accordance with statute and regulation, the error had been corrected and the patent had not expired.

CPI points out that the statute provides for late payment and for correction of error without loss of rights, and that this was achieved. *35 U.S.C. § 41(c)(1)* states:

> **[*1386]** *§ 41(c)(1)* If the Director accepts payment of a maintenance fee after the six-month grace period, the patent shall be considered as not having expired at the end of the grace period.

St. Jude **[**39]** argues that this beneficence does not affect the requirement of *§ 156(a)(1)* that the application for extension must be submitted before patent "expiration," and that the later revival of an expired patent does not overcome this stricture.

When the *'288* patent was issued in 1983, the patentee was a "small entity" and qualified for reduced fees under *35 U.S.C. § 41(h)(1)*. From 1987 to 1998 the patentee paid the maintenance fees at the reduced rate applicable to small entities. However, in 1985 the *'288* patent was non-exclusively licensed to a large entity, triggering the regulatory provision whereby the small entity status is lost to the patentee. See *37 C.F.R. § 1.9(d) (1985)* (providing that small entity status is lost when any rights are licensed to any concern that does not qualify as a small entity). Meanwhile the patent was licensed to Eli Lilly & Company, which does not qualify as a small entity. In 1998 CPI advised the PTO of the error, stated that the erroneous payments as a small entity were made in good faith, and tendered the additional sums due and statutory penalties. The PTO accepted the late payments on October 16, 1998. **[**40]**

St. Jude argues that the patent expired in 1987 when the first incorrect maintenance fee was paid. However, the statute is explicitly contrary. See *35 U.S.C. § 41(c)(1)* ("If the Director accepts payment of a maintenance fee after the six-month grace period, the patent shall be considered as not having expired at the end of the grace period.") A similar issue was considered in *Ulead Systems, Inc. v. Lex Computer & Mgmt. Corp., 351 F.3d 1139 (Fed. Cir. 2003)*, wherein this court confirmed that the patent did not expire.

The district court correctly held that the *'288* patent did not expire, and that the application for term extension was validly submitted. The decision on this issue is affirmed.

Costs

Each party shall bear its costs.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED